of the applicant, and the name and letters or numbers by which the instrument is designated for trade purposes, and the serial number or approximate date of manufacture.

[37 FR 7565, Apr. 15, 1972, as amended at 43 FR 12316, Mar. 24, 1978]

§ 29.34 Revocation of certificates of approval.

MSHA reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, violations of section 109(e) of the Federal Coal Mine Health and Safety Act of 1969 (30 U.S.C. 819(e)), and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval.

§ 29.35 Changes or modification of approved analyzers and detectors; issuance of modification of certificate of approval.

(a) Each applicant may, if he desires to change any feature of an approved analyzer or detector, request a modification of the original certificate of approval issued by MSHA for such instrument by filing an application for such modification in accordance with the provisions of this section.

(b) Applications shall be submitted as for an original certificate of approval, with a request for a modification of the existing certificate to cover any proposed change.

(c) The application shall be accompanied by appropriate drawings and specifications, and by a proposed quality control plan which meets the requirements of Subpart E of this part.

(d) The application for modification, together with the accompanying material, shall be examined by MSHA to determine whether testing will be required.

(e) If the proposed change or modification meets the requirements of this part, a formal certificate of modification will be issued, accompanied, where necessary, by a list of new and revised drawings and specifications covering the change(s) and reproductions of revised approval labels.

[37 FR 7565, Apr. 15, 1972, as amended at 52 FR 17515, May 8, 1987]

§ 29.36 Delivery of changed or modified approved analyzer or detector.

An approved analyzer or detector for which a formal certificate of modification has been issued shall be delivered by the applicant to Approval and Certification Center, Box 201 B Industrial Park Road, Dallas Pike, Triadelphia, W. Va. 26059, as soon as it is commercially produced.

[37 FR 7565, Apr. 15, 1972, as amended at 43 FR 12316, Mar. 24, 1978]

Subpart E—Quality Control

§ 29.40 Quality control plans; filing requirements.

As a part of each application for approval or modification of approval submitted pursuant to this part, each applicant shall file with MSHA a proposed quality control plan which shall be designed to assure the quality of the instrument for which approval is sought.

§ 29.41 Quality control plans; contents.

(a) Each quality control plan shall contain provisions for the management of quality, including: (1) Requirements for the production of quality data and the use of quality control records; (2) control of engineering drawings, documentations, and changes; (3) control and calibration of measuring and test equipment; (4) control of purchased material to include incoming inspection; (5) lot identification, control of processes, manufacturing, fabrication, and assembly work conducted in the applicant's plant; (6) audit or final inspection of the completed product; and (7) the organizational structure necessary to carry out these provisions.

(b) Each provision for final inspection in the quality control plan shall include a procedure for the selection of a sample of the end product and the functional components thereof for testing, in accordance with procedures set forth in Military Standard MIL–STD–105D, ''Sampling Procedures and Tables

for Inspection by Attributes,'' or Military Standard MIL–STD–414, ''Sampling Procedures and Tables for Inspection by Variables for Percent Defective,'' or an approved equivalent sampling procedure, or an approved combination of sampling procedures. Military Standard MIL–STD–105D, ''Sampling Procedures and Tables for Inspection by Attributes,'' and Military Standard MIL–STD–414, ''Sampling Procedures and Tables for Inspection by Variables for Percent Defective'' are hereby incorporated by reference and made a part hereof. These documents are available for examination at Approval and Certification Center, Box 201 B Industrial Park Road, Dallas Pike, Triadelphia, W. Va. 26059 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

(c) The sampling procedure shall include a list of the characteristics to be tested by the applicant or his agent.

(d) The characteristics listed in accordance with paragraph (c) of this section shall be classified according to the potential effect of such defect and grouped in to the following classes:

(1) *Critical.* A defect that judgment and experience indicate is likely to result in hazardous or unsafe conditions for individuals using, maintaining, or depending upon the product; or a defect that judgment and experience indicate is likely to prevent performance of the function of the end product.

(2) *Major.* A defect, other than critical that is likely to result in failure, or to reduce materially the usability of the unit or product for its intended purpose.

(3) *Minor.* A defect that is not likely to materially reduce the utility of the instrument for its intended purpose, or a defect that is a departure from established standards and has little bearing on the effective use or operation of the instrument.

(e) The quality control inspection test method to be used by the applicant or his agent for each characteristic required to be tested shall be described in detail.

(f) Each item manufactured shall be 100 percent inspected for defects in all critical characteristics and all defective items shall be rejected.

(g) The Acceptable Quality Level (AQL) for each major or minor defect so classified by the applicant shall be:

(1) Major—1.0 percent;

(2) Minor—4.0 percent.

(h) Except as provided in paragraph (i) of this section, inspection level II as described in MIL–STD–105D, or inspection level IV as described in MIL–STD–414, shall be used for major and minor characteristics and 100 percent inspection for critical characteristics.

(i) Subject to the approval of MSHA, where the quality control plan provisions for raw material, processes, manufacturing, and fabrication inspection are adequate to ensure control of finished article quality, destructive testing may be conducted at a lower level of inspection than that specified in paragraph (h) of this section.

[37 FR 7565, Apr. 15, 1972, as amended at 43 FR 12316, Mar. 24, 1978]

§ 29.42 Proposed quality control plans; approval by MSHA.

(a) Each proposed quality control plan submitted in accordance with this subpart shall be reviewed by MSHA to determine its effectiveness in ensuring the utility of the instrument for which an approval is sought.

(b) If MSHA determines that the proposed quality control plan submitted by the applicant will not insure adequate quality control, MSHA shall require the applicant to modify the procedures and testing requirements of the plan prior to approval of the plan and issuance of any certificate of approval.

(c) Approved quality control plans shall constitute a part of and be incorporated into any certificate of approval issued by MSHA, and compliance with such plans by the applicant shall be a condition of approval.

§ 29.43 Quality control records; review by MSHA; revocation of approval.

(a) The applicant shall keep quality control inspection records sufficient to carry out the procedures required in MIL–STD–105D or MIL–STD–414, or an approved equivalent sampling procedure.